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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/806,344 | 07/06/2001 | Muneo Tokita | 482842000300 | 8523 |
| 7590 | 05/20/2004 | | EXAMINER | |
| Morrison & Foerster LLP 1650 Tysons Boulevard Suite 300 McLean, VA 22102 | | | SINES, BRIAN J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1743 | |

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|---------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/806,344 | TOKITA ET AL. |
| | Examiner | Art Unit |
| | Brian J. Sines | 1743 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 February 2004.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,2,4-7,12-15,17-25 and 28-36 is/are rejected.

7) Claim(s) 3,8-11,16,26 and 27 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

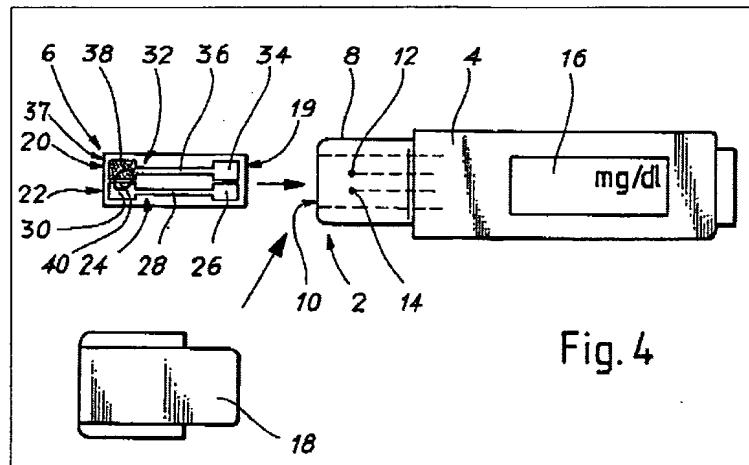
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

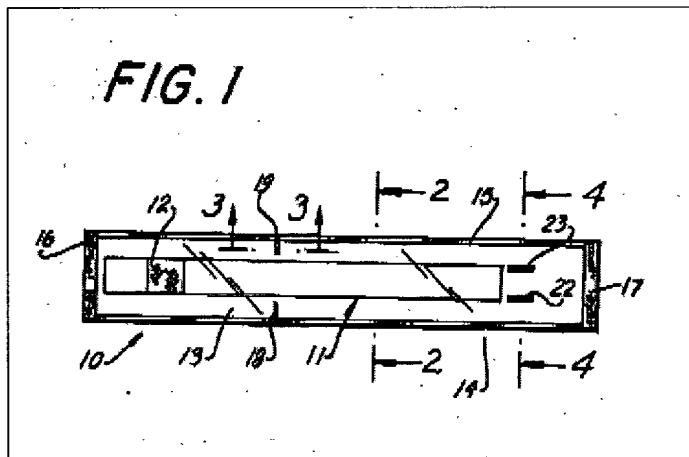
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 2, 4 – 7, 12 – 15, 19 – 22, 29 – 32, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grätzel *et al.* (U.S. Pat. No. 5,378,628 A) in view of Eriksson (U.S. Pat. No. 3,642,450). Regarding claims 1, 29 – 32 and 35, Grätzel *et al.* teach an apparatus comprising: a sensor pack (sensor 6) comprising a sensor chip (collector 37) having a reaction portion (two electrodes 20 & 22) for reacting with a test sample (sample drop 40); and an analyzer device (pen 4) having an opening (cavity 10) for accepting the sensor pack containing one sensor chip, and retaining means (extremity portion 8 & cavity 10) for retaining the sensor chip in the sensor pack accepted through the opening, wherein the analyzer device analyzes an ingredient in a test sample supplied to the reaction portion by detecting a change in the reaction portion (see col. 4, lines 35 – 68; col. 5, lines 1 – 65; figure 4).



Grätzel *et al.* are silent to the specific teaching of incorporating the use of a packaging material covering the sensor chip. However, the use of such protective packaging materials in such diagnostic kits for sensing substrates, such as test strips, are notoriously well known in the art (see MPEP § 2144.03). For example, Eriksson teaches a protective packaging material or an envelope (13) for a sensing material or test strip (11) (see col. 2, lines 50 – 70; col. 3, lines 53 – 75; figure 1). Eriksson does teach the desirability of protecting sensitive test strips from possible contamination in the ambient atmosphere by enclosing them in an envelope or protective packaging material (see col. 1, lines 12 – 39). Eriksson also teaches that the envelope may remain intact and cover a remaining nonindicating portion of the test strip so that the test strip can be held and manipulated without contaminating the test strip (see col. 1, line 72 – col. 2, line 10). Hence, a person of ordinary skill in the art would have recognized the suitability of incorporating the use of a protective packaging material, as taught by Eriksson, with the sensor chip apparatus, as taught by Grätzel *et al.*, for the intended purpose of protecting the sensor chip from contamination (see MPEP § 2144.07). In addition, as is evidenced by Eriksson, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of

incorporating a packaging material with the sensor apparatus of Grätzel *et al.* in order to facilitate the protection of the sensor chip from possible contamination prior to use. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a packaging material with the sensor chip in order to provide protection from possible contamination from the ambient environment prior to use.



Regarding claim 2, Grätzel *et al.* teach that the sensor chip has an engagement means (extremity portion 19) for engagement with the retaining means (extremity portion 8 & cavity 10) (see figure 4). Regarding claim 4, it is inherently anticipated that the sensor pack (6) has a holding, such as an edge, to be held by the user (see figure 4). Regarding claims 5 and 31, it is inherently anticipated sensor pack (6) has a positioning means, such as side edges, for positioning the sensor chip (37) within the opening (10) of the analyzer device (4) (see figure 4). Regarding claim 6, the analyzing device (4) has a positioning means, such as the side edges of the opening (cavity 10), for positioning the sensor chip (37) when only the sensor chip is

inserted through the opening (see figure 4). Regarding claim 7, it is inherently anticipated that the retention means (extremity portion 8 & cavity 10) of the analyzing device (4) can be effectively disengaged in order to remove the sensor chip (37) after use (see figure 4).

Regarding claims 12 and 15, the analyzing device (4) further comprises a reaction information acquisition means (two first electrical contacts 12 & 14 connected to an ammeter) provided within the retaining means (cavity 10) for obtaining information on the reaction at the reaction portion of the sensor chip (see col. 4, lines 35 – 51; figure 4). Regarding claims 19, 22, 35 and 36, Grätzel *et al.* teach that a predetermined orientation of the sensor pack (6) with respect to the direction of insertion into the opening (10) of the analyzing device (4) is prescribed, wherein a cross-sectional shape of the sensor pack as viewed in the direction of insertion when the sensor pack has an orientation different from the predetermined orientation, which is different from the cross-sectional shape of the opening as viewed in the direction of insertion (see figure 4).

Regarding claims 20 and 21, Grätzel *et al.* further teach that the sensor chip (37) has the shape of a generally flat block, wherein the sensor pack (6) and the opening (10) has a shape exhibiting an asymmetry on the opposite sides of the two surfaces of the sensor chip (see figure 4).

Regarding claims 13, 14 and 32, it should be noted that these claims are directed to a system or an apparatus statutory class of invention. Therefore, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus. These claims recite various process or use limitations and are accorded no patentable weight to an apparatus. For example, these claims recite how the apparatus is to be operated, such as by removing a packaging material portion during use, which do not impart any limitations to define the structure of the apparatus being claimed. Process limitations do not add

patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

2. Claims 17, 18, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grätzel *et al.* in view of Eriksson, as applied to claims 1, 2, 4 – 7, 12 – 15, 19 – 22, 29 – 32, 35 and 36 above, and further in view of Crosby (U.S. Pat. No. 6,217,744 B1). Regarding claims 17 and 33, Grätzel *et al.* and Eriksson do not specifically teach the incorporation of a desiccant with the sensor pack. Grätzel *et al.* do teach that the sensor is dried prior to use (see col. 6, lines 32 – 41). Crosby does teach a biological fluid testing apparatus packaged with a desiccant material, such as silica gel, to prevent the inadvertent early activation of the detection system by exposure to fluid (see col. 6, lines 53 – 56). Hence, as evidenced by Crosby, a person of ordinary skill in the art would have recognized the suitability of incorporating a desiccant material with a biological fluid testing apparatus in order to preserve the function of the

apparatus prior to use (see MPEP § 2144.07). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate a desiccant material, as taught by Crosby, with the sensor pack of the apparatus, as taught by Grätzel *et al.*, in order to maintain the function of the sensing apparatus prior to use. Regarding claims 18 and 34, the sensor pack (6) comprises a holding feature, such as side edges, for facilitating the holding of the sensor pack by a user. It would have been obvious to one of ordinary skill in the art to incorporate an accommodation portion with the sensor pack for containing the desiccant material so as to facilitate the effective functional preservation of the apparatus prior to use.

3. Claims 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grätzel *et al.* in view of Eriksson, as applied to claims 1, 2, 4 – 7, 12 – 15, 19 – 22, 29 – 32, 35 and 36 above, and further in view of Baker *et al.* (U.S. Pat. No. 4,654,127). Regarding claim 23, Grätzel *et al.* and Eriksson do not specifically teach the further incorporation of an inserted state detection means for detecting an insertion state of the sensor pack having a detecting portion provided in the analyzing device and a portion to be detected provided in the sensor pack at a predetermined position. However, Baker *et al.* do teach an analysis apparatus (14) that involves the insertion of a test device (12) into a receptacle (62) of the analysis apparatus (14). Baker *et al.* teach that the insertion of the device (12) into receptacle (62) causes the bar code on the bottom of the device (12) to be read by a latent detection means and connects contacts (32A-32E) to analyzer (14) (see col. 9, lines 36 – 40; figure 1). Hence, a person of ordinary skill in the art, as is evidenced by Baker *et al.*, would have recognized the suitability of incorporating a reading or detection means for an analysis apparatus using a test card or sensing chip analysis format in order to facilitate effective apparatus operation and sample analysis (see MPEP §

2144.07). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the reading or detection means, as taught by Baker *et al.*, with the sensing apparatus, as taught by Grätzel *et al.*, in order to facilitate effective apparatus operation and sample analysis. Regarding claim 25, Grätzel *et al.* do not specifically teach the further incorporation of an information holding means for holding information on the sensor chip, wherein the information holding means is provided on at least one of either the sensor pack or sensor chip; and an information recognition means for recognizing information held by the information holding means, wherein the information recognition means is provided on the analyzing device. However, Baker *et al.* do teach that the testing device (12 & 16) incorporates the use of a bar code (47), which provides specific information on performing a specific analysis for the analyzer (14) upon insertion of the device (see col. 4, line 49 – col. 5, line 64; figure 8). Hence, Baker *et al.* recognize the suitability of incorporating a bar code or information holding means with an insertable test device for an analysis apparatus using a test card or sensing chip analysis format in order to facilitate effective apparatus operation and sample analysis (see MPEP § 2144.07). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the use of a bar code or information holding means, as taught by, Baker *et al.*, with an analysis apparatus, as taught by Grätzel *et al.*, in order to facilitate effective apparatus operation and sample analysis.

4. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grätzel *et al.* in view of Eriksson, as applied to claims 1, 2, 4 – 7, 12 – 15, 19 – 22, 29 – 32, 35 and 36 above, and further in view of Lape (U.S. Pat. No. 4,661,319). Grätzel *et al.* and Eriksson do not specifically teach the further incorporation of a speech generation means within the analyzing

device. Grätzel *et al.* do teach that the apparatus is used for the personal detection of blood glucose level, wherein the blood glucose level is indicated by a display (16) (see col. 4, lines 1 – 56; figure 4). Lape teaches a blood glucose testing apparatus that uses a speech generation means to indicate the blood glucose concentration as read by the blood glucose monitor (see col. 7, lines 31 – 63). Therefore, a person of ordinary skill in the art, as evidenced by Lape, would have recognized the suitability of incorporating the use of a speech generation means with a blood glucose monitoring apparatus for the intended purpose of facilitating the effective notification of a blood glucose test result to a user (see MPEP section 2144.07). Both of these indication techniques, the use of a display or speech generation means, as evidenced by Grätzel *et al.* and Lape, respectively, are notoriously well known in the art for being utilized for the same intended purpose, for indicating blood glucose test results. Hence, these indication techniques are considered functional equivalents clearly recognized in the prior art (see MPEP section 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Therefore, it would have been obvious to one of ordinary skill in the art to substitute and incorporate the known equivalent indication technique of using a speech generation means, as taught by Lape, with the analytical detection system, as taught by Grätzel *et al.*, in order to facilitate effective test result notification to the user.

Allowable Subject Matter

Claims 3, 8 – 11, 16, 24 and 26 – 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The cited prior art neither teach or fairly suggest the further incorporation of a retaining means, which penetrates the packaging material at least to reach the sensor chip. The cited prior art neither teach or fairly suggest the further incorporation of a state changing means within the analyzing device for changing the state of the retaining means between a state of receding from the sensor pack and a state of retaining the sensor chip, wherein the state changing means changes the state of the retaining means so that the retaining means is in the receding state when the sensor pack is inserted and so that the retaining means is in the retaining state after the completion of insertion of the sensor pack. The cited prior art neither teach or fairly suggest that the analyzing device further incorporates a first reaction information acquisition means for obtaining information on the reaction at the reaction portions of the sensor chip when the sensor chip is inserted in the state of having a predetermined orientation to the opening; and a second reaction information acquisition means for obtaining information on the reaction at the reaction portion on the sensor chip when the sensor chip is inserted in the opening in the state of having an orientation different from the predetermined orientation. The cited prior art neither teach or fairly suggest the further incorporation within the analyzing device an opening forming means for forming an opening in the packaging material of the sensor pack.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 4 – 7, 12 – 15, 17 – 23, 25 and 28 – 36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

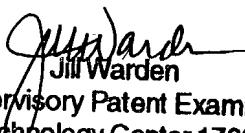
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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